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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,088	07/26/2001	Alessandro Lambiase	026073.00020	6075

4372 7590 03/10/2011  
ARENT FOX LLP  
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SUITE 400  
WASHINGTON, DC 20036

EXAMINER
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WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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03/10/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/890,088	<b>Applicant(s)</b> LAMBIASE, ALESSANDRO	
	<b>Examiner</b> CHERIE M. WOODWARD	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-15, 18-20, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15, 18-20, 33, and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/2011 has been entered.

### **Formal Matters**

2. Claims 1-12, 16, 17, 21-32, 35, and 36 have been cancelled by Applicant. Claims 13-15, 18-20, 33, and 34 are pending and under examination.

### **Response to Arguments**

#### **Rejections/Objections Withdrawn**

3. Rejections drawn to cancelled claims 21, 24-27, 30-32, 35, and 36 are withdrawn as moot in light of the cancellation of these claims. However, to the extent that subject matter from cancelled claims has been incorporated into pending claims under examination, the rejections of record are maintained.

#### **Rejections/Objections Maintained**

##### **Obviousness-Type Double Patenting Rejection**

4. Claims 13, 15, 18-20, and 33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-11, and 13 of copending Application 12/064,172.

Applicant argues that the claims of the '172 are directed to affect the central nervous system and that the optic nerve is not a part of the central nervous system. Applicant argues that the evidentiary reference cited by the examiner "is irrelevant." Applicant also argues that the instant rejection is "not required at this time" and that it should be held in abeyance.

Applicant's arguments have been fully considered, but they are not persuasive. Applicant may decline to accept the evidentiary reference as "irrelevant" but it does not change the elementary-level fact that the optic nerve is a cranial nerve (cranial nerve II, to be exact), which is clearly and unambiguously anatomically classified as part of the central nervous system.

The provisional obviousness-type double patenting rejection is maintained.

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**New Claim Rejections – Necessitated by Amendment**

**Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 13-15, 18-20, 33, and 34 remain rejected under 35 U.S.C. 103(a) as being obvious over Okamoto, JP 10-218787 (18 August 1998) (cited on Applicant's IDS of 7/26/2001; machine language translation of record), for the reasons of record and the reasons set forth herein.

Applicant argues that the administration of 200-500µg/ml of NGF is not taught or suggested by Okamoto. Applicant argues that one would have to engage in hindsight and would not appreciate the unexpected results of using a higher dose to achieve the desired results.

Applicant's arguments have been fully considered, but they are not persuasive. Okamoto teaches an optimizable range from about 0.1µg/250ml to about 100mg/250ml, encompassing Applicant's claimed range (see translation paragraph 51). As previously stated of record, a person of ordinary skill in the art at the time the invention was made would have reasonably known that dosages are results-effective variables which can be optimized. In the case of administering NGF, one of skill in the art would clearly recognize that doses could easily be optimized depending on the intended use and pharmaceutical form, as taught by Okamoto. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977; and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Applicant has presented no evidence showing that the claimed dose range is critical or that it would not have been obvious for one of ordinary skill in the art to determine optimum or workable ranges by routine experimentation based on the express teachings of Okamoto.

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant's hindsight argument ignores both the express teachings of Okamoto and the fact that dose optimization is a results-effective variable that is old and well-known in the pharmaceutical arts.

### **Conclusion**

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHERIE M. WOODWARD** whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647